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JUN 12 2002

510(k) SUMMARY

Submitter Personal Products Company Division of McNeil-PPC Inc.
199 Grandview Road
Skillman, New Jersey 08558-9418

Contact Person Marylou Panico
Mgr. Regulatory Affairs
(908) 904-3709 telephone
(908) 904-3748 telefax

Date Prepared May 29, 2002

Proprietary Name K-Y® Brand Ultra Gel™
Personal Lubricant

Common Name Personal Lubricant

Classification Name Condom 21CFR § 884.5300 Product Code 85HIS

Predicate Device K-Y® Brand LIQUID Personal Lubricant

Description of Device
K-Y® Brand Ultra Gel™ is a non-sterile water- based personal lubricant designed to supplement the body's own natural lubrication fluids. This formula is a clear, non-irritating, non-greasy, non-staining, high viscosity liquid gel. This highly lubricous product may be used with or without a latex condom during intimate sexual activity. K-Y® Brand Ultra Gel™ is not a contraceptive or spermicide. It is however, compatible with latex condoms as demonstrated in Condom Compatibility Testing conducted according the standards defined by ASTM D 3492.

Intended Use
Patient lubricants are devices intended to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device. When used as an accessory to a condom, patient lubricants are deemed Class II Medical Devices.

K-Y® Brand Ultra Gel™ is principally intended as personal lubricant to supplement the body's own natural lubricating fluids, to moisturize, relieve friction and to enhance the ease and comfort of intimate sexual activity. This lubricant may be safely applied to vaginal, anal or penile tissue for lubrication, and moisturization purposes. It is also compatible with latex condoms.

Technological Characteristics
K-Y® Brand Ultra Gel™ formula is proprietary. The product however, has no exceptional technological characteristics, consisting mainly of water-soluble ingredients similar to other lubricants currently on the US market.

510(k) SUMMARY (continued)

Substantial Equivalence

This product has been shown in laboratory testing to be substantially equivalent to its predecessor, the currently marketed K-Y® Brand LIQUID Personal Lubricant. Both devices have the same intended use and similar formulations. One differentiating feature is that K-Y® Brand Ultra Gel™ contains vitamin E and is more lubricious, as demonstrated in laboratory coefficient of friction testing.

Preclinical Testing of Formulation

Preclinical biocompatibility studies on K-Y® Brand Ultra Gel™ Personal Lubricant were conducted by outside laboratories, in compliance with Good Laboratory Practices (GLPs). These studies demonstrated that this formulation was non-irritating, did not produce any significant pharmacotoxic effects and was not associated with system toxicity.

Clinical Testing

In Human Irritation studies under conservative occluded and repetitive conditions, this formulation was non-sensitizing and only mildly irritating.

Consumer-Use Testing conducted to evaluate performance of the proposed formulation as compared to another commercially marketed vaginal moisturizer, demonstrated that the proposed formulation rated significantly higher for texture/consistency and moisturizing properties.

Laboratory, Preclinical and Clinical testing conducted on K-Y® Brand Ultra Gel™ Personal Lubricant has provided scientific evidence that this product is safe for its intended use and substantially equivalent to the predicate device, K-Y® Brand LIQUID Personal Lubricant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2002

Ms. Marylou Panico
Manager Regulatory Affairs
Personal Products Company
Division of McNeil-PPC, Inc.
199 Grandview Road
SKILLMAN NJ 08558

Re: K020827
Trade/Device Name: K-Y® Brand Marque Ultra Gel™ Personal Lubricant
Regulation Number: 21 CFR 880.6375
Regulation Name: Patient lubricant
Regulatory Class: II
Product Code: 85 MMS
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Product Code: 85 HIS
Dated: March 12, 2002
Received: March 14, 2002

Dear Ms. Panico:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) INDICATIONS FOR USE FORM
(Replica of FDA Form)

510(k) Number (if known): K020827

Device Name: K-Y Brand ® Ultra Gel™ Personal Lubricant
Indications For Use:
Personal Lubricant compatible with latex condoms, helps enhance intimacy

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-the-Counter-Use ✓
(per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020827

JUN 12 2002